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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|----------------------|-------------------------|------------------|
| 10/087,207 | 02/28/2002 | Patrick Jay Lutz | 5408/11295-US2 | 7037 |
| 7278 7 | 590 03/03/2003 | | | |
| DARBY & DARBY P.C. | | | EXAMINER | |
| P. O. BOX 5257 NEW YORK, NY 10150-5257 | | | PRYOR, ALTON | NATHANIEL |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1616 | 11 |
| | | | DATE MAILED: 03/03/2003 | // |

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

Office Action Summary

Applicant(s)

10/087,207

Art Unit

Examiner Alton Pryor

1616



| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | |
|--|---|--|--|--|--|
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. • Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the | | | | | |
| mailing - If the po If NO po Failure to - Any rep | date of this communication. eriod for reply specified above is less than thirty (30) days, a reply within th | e statutory minimum of thirty (30) days will be considered timely. nd will expire SIX (6) MONTHS from the mailing date of this communication. e application to become ABANDONED (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1)[X] | Responsive to communication(s) filed on $\underline{\textit{Dec 12, 2}}$ | 002 . | | | |
| 2a) 🗌 | This action is FINAL . 2b) ☑ This acti | on is non-final. | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | |
| 4) 💢 | Claim(s) <u>1-50</u> | is/are pending in the application. | | | |
| ³ 4a) Of the above, claim(s) 2, 3, 7-10, 13, 15-17, 19-21, 23, 28-31, 44, and 4 is/are withdrawn from consideration. | | | | | |
| 5) 🗆 | Claim(s) | is/are allowed. | | | |
| 6) 💢 | Claim(s) 1, 4-6, 11, 12, 14, 18, 22, 24-27, 32-43, | and 46 is/are rejected. | | | |
| 7) 💢 | Claim(s) <u>47-50</u> | is/are objected to. | | | |
| 8) 🗆 | | are subject to restriction and/or election requirement. | | | |
| Application Papers | | | | | |
| 9) 🗆 | The specification is objected to by the Examiner. | | | | |
| 10) | The drawing(s) filed on is/are | a) \square accepted or b) \square objected to by the Examiner. | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) | The proposed drawing correction filed on | is: a) \square approved b) \square disapproved by the Examiner. | | | |
| | If approved, corrected drawings are required in reply to this Office action. | | | | |
| 12) 🗆 | The oath or declaration is objected to by the Examin | ner. | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) 🗀 | All b)□ Some* c)□ None of: | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2 | $2.\square$ Certified copies of the priority documents have | e been received in Application No | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| *See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). | | | | | |
| a) Untranslation of the foreign language provisional application has been received. | | | | | |
| 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | |
| Attachment(s) 1) X Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s) | | | | | |
| | ice of Draftsperson's Patent Drawing Review (PTO-948) | 5) Notice of Informal Patent Application (PTO-152) | | | |
| | mation Disclosure Statement(s) (PTO-1449) Paper No(s). 5,9 | 6) Other: | | | |

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Election Requirement

The elected composition is allowable. The elected composition is in Table 8 on page 18 of the specification. A specific benzethonium salt was not elected. However, Examiner's search revealed methyl benzethonium chloride. Since no specific benzethonium salt was elected by Applicant, Examiner is treating methyl benzethonium chloride as the elected salt.

Claim Rejections under 35 U.S.C. 112, 2nd paragraph

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 6,45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 3. Claim 6 recites the limitation "R4 is benzyl" in line 1. There is insufficient antecedent basis for this limitation in the claim.
- 4. Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: related to what object is the composition being applied to.

Claim Rejection under 35 U.S.C. 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Miles et al (US 3236730; 2/22/66). Miles teaches a composition comprising 0.05% to 0.5% methyl benzethonium chloride and 0.5% to 2% salicylic acid. The composition is used by ophthalmologists to control dermatological bacterial disorders of the eye. See column 1 lines 10-48, claim 1. Although the reference does not teach that the combination is synergistic, it is inherent that the prior art combination would have been synergistic at the time of the invention since the present composition can comprise 0.5% salicylic acid and 0.45 % benzethonium chloride (see instant claim 41). Note that the prior art ranges and instant ranges overlap for both the benzethonium chloride compound and the carboxylic acid compound (salicylic acid). Therefore, it is anticipated that the prior art composition would have been synergistic at the time the invention was made.

Claim Rejection under 35 U.S.C. 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,4,5,11,12,14,18,22,24,27,32-43,46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miles et al (US 3,236,730; 2/22/66) and JP 11279205; 10/12/99. Miles teaches

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a composition comprising 0.05% to 0.5% methyl benzethonium chloride, 0.5% to 2% salicylic acid and resorcinol (alcoholic compound - solvent). The composition is used by ophthalmologists to control dermatological bacterial disorders of the eye. See column 1 lines 10-48, claim 1. See 102 (b) rejection above. Miles teaches all that is recited in the claims except for the composition comprising dehydroacetic acid. However, JP '205 teaches an ophthalmological composition used by ophthalmologists to control corneal dryness comprising dehydroacetic acid. See abstract. It would have been obvious to one having ordinary skill in the art to modify the invention of Miles to include the dehydroacetic acid taught by JP '205. One would have been motivated to do this so that Miles composition does only control disorders of the eye associated with bacterial infection but also would have the capability of preventing corneal dryness at the same time.

Claim Objection

Claims 47-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest a composition comprising dehydroacetic acid plus a benzethonium salt plus salicylic acid plus benzoic acid plus phenoxyethanol plus benzyl alcohol.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

Art Unit:

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Alton Pryor

ALTON N. PRYOR
Primary Examiner

3/2/03